K102188

510(k) SUMMARY AUG - 9 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information: DFI Co., Ltd
542-1, Daman-ri, Jinrye-myun, Kimhae-city,
Gyung-nam, (621-880), Korea

Contact Person: Ho Dong, Yang
Onbix Corporation
#708 Le-Meilluer Town, 837-19 Yeuksam-dong
Gangnam-gu, Seoul, Korea
Tel: *82-2-566-3360 / Fax: *82-2-6280-3360
Email: onbix@naver.com

Date Summary Prepared: **Aug 05, 2011**

Device Name:

Trade Name(s):	CYBOW Reader 300, CYBOW Reader 720
Classification Name:	Urinalysis system
Panel:	clinical chemistry
Product code:	KQO, JIL, JIO, CDM, CEN, JIN, JIR, JJB, JMA, JMT, LJX

Predicate Device Information:
K926359 / Clinitek 200+, 500

Device Description:
CYBOW Reader 300, 720 are reflectance photometer. The strip is illuminated by white light, and there flected light from the strip is detected by a color Image Sensor. The RGB signals are digitized, and this digitized image is evaluated by the processor. The intelligent image analyzer SW locates the strip and the pads, and based on these color data the parameter values are determined. The results with the date and time of the measurement as well as the sequence number and the ID are stored and printed out by the internal printer.

Intended Use:
The CYBOW Reader 300 and CYBOW Reader 720 urine chemistry analyzers are semi-automated analyzers intended to be used with CYBOW 11 and CYBOW 10 Reagent Strips as a test system to semi-quanititatively or qualitatively measure the specified analytes in urine as follows: glucose, urobilinogen, pH, ketone, occult blood, protein, bilirubin, ascorbic acid, nitrite, leukocyte, and specific gravity. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. The CYBOW Reader 300 and CYBOW Reader 720 urine chemistry test systems are intended for prescription and in vitro diagnostic use only.

Comparison to Predicate Device(s):
This device is equivalent to the predicate devices in its intended use and technological characteristics, including:

* indications for use
* technological characteristics
* performance properties

Non-Clinical Study performance
Non-Clinical study was conducted on the CYBOW Reader 300 and CYBOW Reader 720 such as;

1. Analytical performance
   precision / reproducibility linearity / assay reportable range, detection limit, analytical specificity / limitation of test,
2. Comparison study
   Method comparison with predicate device, clinical study

The evaluation followed "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002) NCCLS, EP9A.
Three independent laboratory evaluations of the New Device and Predicative Device were conducted. One evaluation one was Samsung Hospital (Site A, sample number: 255samples), the other was Authoritative local university hospital (Hospital at national Univ.of Pusan) (Site B, sample number: 280samples) and another was Authoritative local university hospital (Hospital at national Univ.of Dong Ai) (Site C, sample number: 332samples) for 20days. Three operators, reflective of the intended users of the devices, performed the testing at each site

Conclusion
Based on the information provided in this summary we conclude that CYBOW Reader 300 & 720 Urinalysis system are safe and effective and substantially equivalent to the predicate device K926359.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 09 2011

DFI Co., Ltd
c/o Mr. Ho Dong Yang
CEO, Onbix Corporation
#821 Samil Plaza, 837-26 Yeuksam-dong
Gangnam-gu, Seoul
Republic of Korea, 135-937

Re: k102188
Trade/Device Name: CYBOW Reader 300 and CYBOW Reader 720 Urine Chemistry Analyzers
Regulation Number: 21 CFR §862. 1340
Regulation Name: Urinary glucose (non-quantitative) system
Regulatory Class: Class II
Product Code: JIL, JIO, CDM, CEN, JIN, JIR, JJB, JMT, JRE, LJX, JMA, KQO
Dated: July 20, 2011
Received: July 26, 2011

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K102188

Device Name: CYBOW Reader 300 / CYBOW Reader 720

Indications for Use:

The CYBOW Reader 300 and CYBOW Reader 720 urine chemistry analyzers are semi-automated analyzers intended to be used with CYBOW 11 and CYBOW 10 Reagent Strips as a test system to semi-quanititatively or qualitatively measure the specified analytes in urine as follows: glucose, urobilinogen, pH, ketone, occult blood, protein, bilirubin, ascorbic acid, nitrite, leukocyte, and specific gravity. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. The CYBOW Reader 300 and CYBOW Reader 720 urine chemistry test systems are intended for prescription and in vitro diagnostic use only.

Prescription Use _____X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K102188